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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/813,091 | 03/19/2001 | Walter J. Ledergerber | 263/103 | 2870 |

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| EXAMINER |
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ISABELLA, DAVID J

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| ART UNIT | PAPER NUMBER |
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3738

DATE MAILED: 07/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/813,091

Applicant(s)

LEDERGERBER, WALTER J.

Examiner

DAVID J ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,13-99,101-110,112-114 and 116-153 is/are pending in the application.
- 4a) Of the above claim(s) 15-93 and 127-153 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,13,14,94-99,101-110,112-114 and 116-126 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Status of the Claims

Claims 1,3,4,13-99,101-110,112-114,116-153 are pending in the application. Claims 15-93 are withdrawn from consideration. Newly submitted claims 127-153 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the new claims are directed to newly presented features which were not originally present in the elected invention. The newly added features of the troughs being cuts; additional channels intersecting the parallel channels; the channels being cut; the ridges extending continuously across the sheet; individual villi of ePTFE;

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 127-153 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,3,4,13,14, 94-99,101-110,112-114,116-153 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter not described in the specification in such a way as

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to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The features as claimed were not present in the originally filed specification.

Claims 105-109 and 123-126 recite features that find no support in the specification as originally filed.

According to the MPEP, section 608.01(p), if an application as filed incorporates essential material by reference to a U.S. patent, applicant may be required prior to examination to furnish the Office with a copy of the referenced material together with an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the copy consists of the same material incorporated by reference in the referencing application.

Applicant has failed to provide a copy of a printed U.S. patent, in lieu of the affidavit or declaration. Therefore, incorporation of the essential subject matter of applicant's earlier patent is improper and the rejections to the claims under 35 USC 112 first paragraph stands.

Additionally, incorporation of essential material may not be incorporated by U.S. patent or application which itself incorporates "essential material" by reference. Since this application forms a continuity chain integrating eight earlier filed applications, the current subject matter to be incorporated relies on US Patents which, itself, incorporates essential material.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 94, 116-121 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 94 as worded is inaccurate. The claim defines the ridges and troughs as having regions of varying heights however relying on figure 10, only the ridges have varying heights and the troughs appear to lie in the same plane.

Claims 116-121 are indefinite. These claims are directed to a combination of the sheet and a device. The preamble of claim 1 does not support the inclusion of a combination of the sheet and a device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,3,13,14,95-98,101,122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Netto (4573999) in view of Mikulich et al (4651721).

Netto discloses a sheet having a first surface and a second surface for implantation in a body. The inner surface of the sheet of Netto is non-textured and the outer surface is textured with a plurality of continuous parallel troughs. See column 3, lines 3+. Netto uses silicone as the material of choice for the membrane, however Mikulich et al teaches that silicone and ePTFE are equivalent materials used in the art for soft tissue application. When better control of the membrane's expansion or response to the applied force is required, ePTFE offers the surgeon anisotropic properties to meet the designed parameters. To replace silicone with ePTFE in Netto, to better control the membrane's response to applied forces, would have been obvious to one with ordinary skill in the art from the teachings of Mikulich et al.

Claim 3, the concentric troughs are in nested configuration as broadly claimed.

Claim 13, the limitation of "less textured" is fully met by the non-textured surface of Netto.

Claim 14, see Mikulich et al as applied in claim 1 supra.

Claim 95, the concentric troughs of Netto forms a pattern as broadly claimed.

Claim 96, the pattern of Netto is a wave form and therefor inherently possesses periodic characteristic.

Claims 97-98, see column 3, lines 17-20.

Claim 101, see concentric pattern of the exterior surface. (column 3, lines 5-7)

Claim 122, see troughs of Netto.

R sponse to Argum nts

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3579 for regular communications and 703-305-3580 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



DAVID J ISABELLA
Primary Examiner
Art Unit 3738

dji
July 8, 2003